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PATENT
Our Docket: P-UC 4679

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Civelli and Lin	Examiner: R. Deberry
Serial No: 09/932,161	Group Art Unit: 1647
Filed: August 17, 2001	
For: SCREENING AND THERAPEUTIC METHODS FOR PROMOTING WAKEFULNESS AND SLEEP	

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Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

Responsive to the Restriction Requirement mailed December 2, 2002, consideration of the following remarks is respectfully requested.

Claims 1-33 are pending, and have been restricted under 35 U.S.C. § 121 into the following six groups:

Group I : Claims 1-10 and 13, directed to a method of screening for a PrRP receptor agonist that promotes wakefulness;

Group II : Claims 1, 14 and 15, directed to a method involving administering a PrRP receptor agonist that promotes wakefulness;

Group III : Claims 1, 11 and 12, directed to a method of screening for a PrRP receptor agonist that promotes wakefulness wherein the agonist promotes interaction of PrRP receptor with an AMPA receptor associated protein;

Group IV : Claims 16-27 and 31, directed to a method of screening for a PrRP receptor antagonist that promotes sleep;

Group V : Claims 16, 28, 29 and 30, directed to a method of screening for a PrRP receptor antagonist that promotes sleep, wherein the antagonist reduces interaction of PrRP receptor with an AMPA receptor associated protein; and

Group VI : Claims 16, 32 and 33, directed to a method involving administering a PrRP receptor antagonist that promotes sleep.

Applicants traverse the Restriction Requirement for the reasons stated below. Nevertheless, in order to be responsive to the Office Action, Applicants elect the claims of Group I, claims 1-10 and 13, directed to methods of screening for a PrRP receptor agonist that promotes wakefulness. Applicants reserve the right to pursue prosecution of the non-elected claims in one or more applications that claim the benefit of priority to the above-identified application.

Applicants traverse the Restriction Requirement on the grounds that search and examination of the entire application would not pose a serious burden on the Examiner. In this regard, the invention relates to the determination that modulating PrRP receptor activity effectively modulates wakefulness in mammals. All pending claims recite a functional relationship between PrRP receptor agonism or antagonism and either promoting wakefulness or decreasing wakefulness (promoting sleep). Therefore, a thorough search of art relating to PrRP and its biological function would likely reveal art relevant to all six groups of claims. For this reason, Applicants respectfully submit that search and examination of the claims of Groups I through VI together does not pose a serious burden on the Examiner.

Regarding Groups I and IV

In particular, Applicants point out that search and examination of the claims of Groups I and IV would not pose a serious burden on the Examiner because, although patentably distinct, both groups of claims are directed to methods that involve providing a compound that modulates PrRP receptor (an agonist or antagonist) and determining the ability of that compound to promote wakefulness or promote sleep (i.e. reduce wakefulness) in a mammal. Because the claims all recite the same receptor (PrRP receptor) and involve determining the ability of a compound to modulate a biological activity of this receptor (wakefulness and sleep), Applicants submit that a thorough search of the elected claims of Group I will include art relevant to the claims of Group IV. Notably, Groups I and IV are both classified

in class 435, subclass 7.1. As such, Applicants submit that examination of the claims of Groups I and IV together would not pose an undue burden on the Examiner, and request rejoinder of at least the claims of Groups I and IV.

Regarding Groups I and II

Applicants submit that restriction of claims 1 and 14, as they relate to administration of a compound to a mammal, to Group II is improper. In this regard, the specification teaches that determining the ability of a compound to promote wakefulness or sleep (step (b) of claim 1) involves an *in vivo* assay (page 43, lines 5-8). In such an assay, the compound would be administered to a mammal. Furthermore, Applicants submit that search and examination of the claims of Groups I and II together would not pose an undue burden on the Examiner because a search of methods of identifying a PrRP receptor agonist that promotes wakefulness (Group I claims) will necessarily reveal art relating to administering the compound to a mammal to promote wakefulness (claim 15). Therefore, Applicants request rejoinder of the claims of Group II with the elected claims of Group I.

Similarly, Applicants submit that restriction of claims 16 and 32, as they relate to administration of a compound to a mammal, to Group VI is improper. Applicants further submit that search and examination of the claims of Groups IV and VI together would not pose an undue burden on the Examiner because a search of methods of identifying a PrRP receptor antagonist that

promotes sleep (Group IV) will necessarily reveal art relating to administering the compound to a mammal to promote sleep (claim 33). Therefore, Applicants request that Groups IV and VI be rejoined and examined together with the elected claims of Group I.

Regarding Groups I and III

Applicants submit that search and examination of the claims of Groups I and III together would not pose an undue burden on the Examiner. Although patentably distinct, the claims of Group III depend from claim 1, and are directed to screening for a compound for promoting wakefulness in a mammal wherein step (a) further involves identifying a compound that promotes interaction of PrRP receptor with an AMPA receptor associated protein. Applicants respectfully submit that searching various alternatives for performing step (a) of independent claim 1 (Group I), as recited in dependent claims 11 and 12 (Group III), does not pose a serious burden on the Examiner. Similarly, searching various alternatives for performing step (a) of claim 16 (Group IV) as recited in dependent claims 28, 29 and 30 (Group V) does not pose a serious burden on the Examiner. Further, it is noted that the claims of Groups I and III are classified in the same search class, and that the claims of Groups IV and V are classified in the same search class. Therefore, Applicants request rejoinder of Group III with the elected claims of Group I, and further request rejoinder of Group I claims with those of Groups IV and V.

CONCLUSION

In view of the remarks submitted herein, Applicants respectfully request that claims 1-10 and 13 of Group I be examined. In addition, Applicants request reconsideration of the Restriction Requirement and rejoinder of all Groups, or at least Groups I, II and IV, for the reasons set forth above. The Examiner is invited to call the undersigned agent or Cathryn Campbell if there are any questions regarding this application.

Respectfully submitted,

January 2, 2003
Date

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AMENDMENT TRANSMITTAL LETTER			DOCKET NUMBER: P-UC 4679
SERIAL NO: 09/932,161	FILING DATE: August 17, 2001	EXAMINER: R. Deberry	GROUP ART UNIT: 1647
INVENTION: SCREENING AND THERAPEUTIC METHODS FOR PROMOTING WAKEFULNESS AND SLEEP			

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(SIGNATURE OF PERSON MAILING PAPER OR FEE)

Transmitted herewith is a Response to Restriction Requirement, mailed December 2, 2002, in the above-identified application.

X Small Entity status of this application has been established under 37 CFR 1.27.

___ Petition for Extension of Time is enclosed (in duplicate).

___ Terminal Disclaimer with fee under 37 C.F.R. 1.20(d) is enclosed.

X No additional claims fee is required.

___ An additional claims fee is required and has been calculated as shown below:

CLAIMS AS AMENDED

	NUMBER AFTER AMEND-MENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		NUMBER OF EXTRA CLAIMS PRESENTED		RATE			FEE	
							SMALL ENTITY	OTHER ENTITY		SMALL ENTITY	OTHER ENTITY
TOTAL CLAIMS	33	-	33	-	0	x	$9	$18	=	$0	$
INDEPEN-DENT CLAIMS	4	-	4	-	0	x	$42	$84	=	$0	$
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM			____YES		___X___NO		$140	$280	=	$0	$
							TOTAL ADDITIONAL FEE			$0	$

* If the "HIGHEST NUMBER PREVIOUSLY PAID FOR" is less than 20, write "20" in this space.

** If the "HIGHEST NUMBER PREVIOUSLY PAID FOR" is less than 3, write "3" in this space.

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___ Please charge my Deposit Account No. 03-0370 the amount of $_____. A duplicate copy of this sheet is enclosed.

___ A check in the amount of $ is enclosed, $ of which covers the fee for a -month extension of time.

_X_ The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment to Deposit Account No. 03-0370. A duplicate copy of this sheet is enclosed.

_X_ The Commissioner is hereby authorized to charge to Deposit Account No. 03-0370 any fees under 37 CFR 1.17 which may be required under 37 CFR 1.136(a)(3) for an extension of time in any concurrent or future reply requiring a petition for extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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